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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
097064,600	04/21/98	ELIA	J 796-F-12

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GM31/0527

EXAMINER	
LUCHESI, N	
ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 05/27/99

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

## Office Action Summary

Application No.	09/064,000	Applicant(s)	Elia
Examiner	Lucchesi	Group Art Unit	3732

--The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address--

### Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- Responsive to communication(s) filed on \_\_\_\_\_.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- Claim(s) 1 - 5 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) 1 - 5 is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  Interview Summary, PTO-413
- Notice of References Cited, PTO-892  Notice of Informal Patent Application, PTO-152
- Notice of Draftsperson's Patent Drawing Review, PTO-948  Other \_\_\_\_\_

## Office Action Summary

Art Unit: 3303

**DETAILED ACTION**

*Continuing Status*

1. The oath in this application indicates that benefit is claimed of parent application 08/837,608. However, no other indication is provided as to whether this application is a continuation, or a CIP of that application.

*Drawings*

2. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

*Claim Rejections - 35 USC § 101*

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims in this application recite a method of forming an organ in the body, as well as a composition for producing a germinal organ for implantation, as well as a gene and living cells.

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A claim drawn to a non-plant multicellular organism (an organ) or a naturally occurring article which has not been altered is not considered "new" under 35 USC 101. In this case, the article has not been significantly altered such as to impart a patentable distinction from the same naturally occurring multicellular living organism. American Fruit Growers v. Broadex, 283 U.S. 1, 8, USPQ 131 (1931).

5. Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The method of forming an organ in the body, as well as the composition for producing an organ for implanting in the body would not be accepted as obviously valid by one of ordinary skill in the art. The allegation that organs can be created and grown either in vivo or in vitro borders on the incredible to one of ordinary skill in the art. This rejection might be overcome by submitting evidence in affidavit form, such as the results of scientific tests, conducted or witnessed by competent, disinterested third parties. Such tests should include proper scientific controls. Mere testimonials from patients would likely be of little value, for obvious reasons.

### *Specification*

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The specification is objected to under 35 USC 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

The disclosure is non enabling for the creation of an organ. Because such allegations border on the incredible, one skilled in the art would not be able to make or use the invention as recited and claimed. It is held that which is impossible, cannot be enabled.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nick Lucchesi whose telephone number is (703) 308-2698.

*Nick Lucchesi*  
Nick Lucchesi

May 26, 1999

*Nicholas D. Lucchesi*

Nicholas D. Lucchesi  
Primary Examiner